REMARKS/ARGUMENTS

New claims 43-46 correspond to the original claims 1 and 21 and subject-matter disclosed in the application as filed, in particular on page 6, lines 21-23; page 7, lines 22-23; page 15, lines 3-10, 16-18 and page 19, lines 23-27. See also page 7, lines 17-20 and page 11, lines 1-7.

New claim 47 corresponds to subject-matter of the original claim 18 and subject-matter disclosed in the application as filed, in particular on page 6, lines 21-23, 30; page 7, lines 22-23; page 8, line 4-7; page 15, lines 3-10, 16-18 and page 19, lines 23-27.

New claim 48 corresponds to subject-matter disclosed in the application as filed on page 15, lines 15-18. New claim 49 corresponds to subject-matter disclosed in the application as filed on page 15, lines 23-24. New claim 50 corresponds to subject-matter disclosed in the application as filed on page 15, lines 23-26. New claim 51 corresponds to subject-matter disclosed in the application as filed on page 7, line 30 – page 8, line 4 and page 16, lines 4-11.

New claim 52 corresponds to subject-matter of the original claim 17 and subject-matter disclosed in the application as filed, in particular on page 7, line 30 – page 8, line 4. New claims 53-55 correspond to the original claims 12, 13 and 16. New claim 56 corresponds to subject-matter disclosed in the application as filed on page 8, line 29 – page 9, line 4 and Figs. 4, 5, 7, 10a and 10b. New claim 57 corresponds to subject-matter disclosed in the application as filed on page 11, lines 1-7. No new matter has been entered.

The title has been changed as requested. Applicants appreciate the withdrawal of the 112 rejection and the rejection over WO 00/64519.

In the Office communication the following prior art documents were cited in rejections that have been maintained:

Davies et al. US 2002/0053344 A1

Davies discloses an inhalation device that uses a medicament pack that comprises two sheets peelably secured to one another (paragraph [0004], [0041]). These two sheets define a plurality of medicament containers spaced along the length of the sheets (paragraph [0005]). In connection with inhalation, the two sheets are peeled apart a sufficient portion to expose the contents of a dose pocket, which is being brought into alignment with a slot that is in connection with a nozzle (paragraph [0050]).

The nozzle of the inhaler taught by Davies is fixed relative the peelable blister during inhalation. Thus, Davies does not teach a DPI that includes an arrangement for providing a relative motion between the nozzle and a dose bed during the course of a single inhalation. The design of Davies can furthermore not be modified in any obvious way to provide such a relative motion that allows the nozzle to pass over the combined dose for a simultaneous or sequential delivery of the at least two medicament during a single inhalation.

Applicant also notes its previous point of view that the only discussion of a combined delivery taught by Davies is the subject-matter disclosed by paragraph [0094]. In this paragraph it clearly says that the active ingredients are provided as combinations, i.e. in a ***mixture*** form. Such a *mixture* form cannot in itself fulfil the features of the claims in terms of having a dose bed onto which the at least two medicaments are deposited *individually*.

Regardless, as Davies does not disclose nor is even compatible with the provision of a relative motion between the nozzle and the dose bed, the new claims are clearly novel and non-obvious over Davies.

Clarke discloses inhalable compositions containing formoterol and fluticasone. Clarke discloses compositions in solution and dispersion forms as well as dry powder form.

Clarke teaches that a dry powder composition comprising a unit dose of selected amounts of formoterol and fluticasone in a ***mixture*** together with a suitable carrier (excipient) may be loaded into a capsule or blister (paragraph [0012]). The capsule or blister may then be made available in a dry powder inhaler and the powder mixture administered to a user.

Clarke does not disclose any DPI that has an arrangement for providing a relative motion between a nozzle and a dose bed to allow the nozzle to pass over the combined dose on the bed for a simultaneous or sequential delivery of the at least two medicaments during the course of a single inhalation.

Clarke does actually not disclose any DPI at all but merely refers to two patent documents disclosing a DPI for using capsules or a multidose DPI. However, neither of these DPI solutions is able to provide a relative motion between a nozzle and a dose bed during inhalation.

Therefore the new claims are both novel and non-obvious over Clarke.

The Examiner has in connection with Clarke assumed that the larger lactose excipient particles will cause the two medicaments formoterol fumarate and fluticasone propionate to be inherently separated and thereby not detrimentally interact. Such an assumption is one of first impression for Applicant, who requests the Examiner to provide evidence supporting the assumption that the inclusion of a relative large amount of larger excipient particles will prevent any physical interaction between two medicaments that are mixed together with the excipient. Notwithstanding this issue, the new claims are patentable even if it remains unresolved.

Accordingly, and because none of the references either alone or in combination disclose or suggest the subject matter of the newly presented claims, Applicants respectfully request the reconsideration and withdrawal of the outstanding rejections.

Finally, several provisional double patenting rejections have been presented. However, the claims have been changed herein, and in addition this case appears to be the first in line for Issuance. Accordingly, it is requested that this case be allowed to issue first, and that as the cases noted in the double patenting rejections proceed through examination and issue that the possibility of double patenting then be considered there against the fixed, issued claims deriving from this application.

Respectfully submitted,

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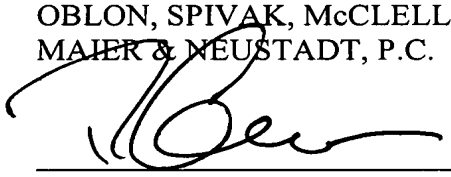
MAIER & NEUSTADT, P.C.



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